

In-Store Concept Test

Marketing Roundtables Inc. Minneapolis, MN December 1998

Methodology

A concept test was conducted among consumers in Minneapolis grocery stores. They were each presented one of three concepts (**code 10, code 20, or code 30**). The concept was removed, and they were asked to describe in their own words what was the main or most important message the statement was telling them.

The following claims each appeared on a board picturing four cereal boxes:

Code 10 (FDA) – “Diets high in fiber-containing grain products, fruits and vegetables, and low in fat may reduce the risk of some cancers, a disease associated with many factors.”

Code 20 (FDA) – “Diets rich in fiber-containing grain products, fruits and vegetables and low in saturated fat and cholesterol may reduce the risk of heart disease, a disease associated with many factors.”

Code 30 (Authoritative) – “Diets rich in whole grain cereals and other plant foods may reduce the risk of coronary heart disease and certain cancers.”

Code 10 and Code 20 are current FDA-approved claims. **Code 30** represents the authoritative statement from the NAS Diet and Health Report (NAS, 1989).

Results

The table below sets forth the percentages of consumers mentioning whole grain as part of their message recall.

	Whole Grain
Code 10 (FDA) n=50	6%
Code 20 (FDA) n=50	12%
Code 30 (Authoritative) n=50	26%

Conclusion

The proposed claim (NAS, 1989), **code 30**, succeeded in more than doubling consumer recall of whole grain as part of the message.

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July 6, 1999

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VIA FACSIMILE AND REGULAR MAIL

Ms. Christine Lewis (TIFS-451)
Deputy Director
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

Re: *General Mills, Inc.; Whole Grain Foods Authoritative Statement Claim Notification*

Dear Ms. Lewis:

On behalf of General Mills, Inc. ("General Mills"), I make the following supplements to the "Whole Grain Foods Authoritative Statement Claim Notification," submitted by Patton Boggs LLP, on behalf of General Mills, on March 10, 1999. These amendments are made without prejudicing the 120-day notification period set forth in section 303 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA").¹

1. Difference from Existing Claims

The notification is amended to include the following statement on page 27, immediately following the last paragraph of section VII, "Consistency with Currently Authorized Health Claims," and preceding section VIII, "Conclusion":

"The whole grain foods claim is not equivalent to any authorized health claims, including those for fiber. The whole grain foods claim refers to 'diets rich in whole grain foods and other plant foods,' as opposed to fiber-containing foods. Rather than fiber being a food component referred to in the claim as necessary for the beneficial relationship, the whole

¹ Pub. L. No. 105-115 (November, 21, 1997).

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grain claim recognizes the explicit wording, and intended meaning, of the authoritative statement: whole grain foods themselves have a beneficial effect that cannot be attributed to fiber, or any other single component of the foods. Furthermore, because diets that satisfy the whole grain claim, do not necessarily satisfy the fiber claims, and vice versa, the claims are clearly mutually exclusive. Thus, the proposed whole grain foods claim satisfies FDAMA's requirements because it is appropriately based on an authoritative statement, and is not equivalent to an already-authorized health claim."

2. Model Claim

The model claim set forth on page 10 of the notification is amended to read:

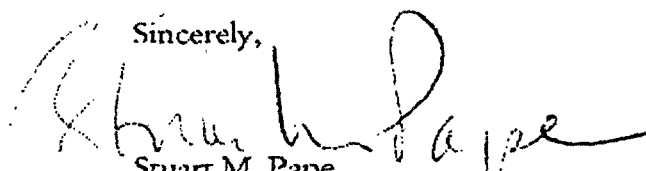
Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.²

The amended model claim includes the concept that a diet should be low in saturated fat and cholesterol (as well as low in total fat and rich in whole grain foods and other plant foods) in order to have the potentially beneficial effects on heart disease risk.

3. Confidentiality

General Mills does not object to the Food and Drug Administration making public the March 10, 1999, notification, and this letter, on July 8, 1999, the day the 120-day notification period set forth in FDAMA expires and the claim takes effect.

Sincerely,



Stuart M. Pape
Counsel, General Mills, Inc.

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² The claim would not need to refer to "saturated fat and cholesterol" if the disease endpoint in the claim were only "certain cancers."